ArthroCare CORPORATION

MAY 0 2 2002

510(k) Summary

ArthroCare Corporation
Visage® Wands

K020408

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Establishment Registration Number:	2951580
Phone:	(408) 736-0224
Contact Person:	Bruce Prothro Vice President, Regulatory Affairs, Quality Assurance, and Clinical Research
Date Prepared:	February 6, 2002

Device Description

Trade Name:	Visage® Wands
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

ArthroCare® Electrosurgery System	K001302
Visage® Cosmetic Surgery System	K003624
Coherent Ultrapulse CO_2 Laser	K963339
Ellman Surgitron IEC	K980177
Ethicon PowerStar Bipolar Scissors	K981361
MedArt Uni-Laser 450P CO_2 Laser System & Accessories	K991297

Product Description

The Visage Wands are bipolar, high frequency electrosurgical devices designed for general dermatological, cosmetic, plastic, and reconstructive procedures.

Intended Use

The Visage Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in general dermatology, cosmetic, plastic, and reconstructive surgery including:

- Abscesses
- Aponeurotic Repair
- Basal Cell Carcinoma
- Biopsy
- Blepharoplasty
- Cosmetic Repairs
- Cysts
- Epithelioma
- Keratosis
- Mammaplasty
- Nevi (Moles)
- Oculoplastic Procedures
- Panniculectomy
- Papilloma Keloids
- Pedicle Flap
- Rhytidectomy
- Development of Skin Flaps
- Skin Tags
- Skin Resurfacing for Treatment of Wrinkles, Rhytides, and Furrows
- Verrucae (Warts)

Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials incorporated, product specifications, and energy requirements of those systems. Additionally, performance testing has been completed to demonstrate the safe and effective use of the Visage Wands in the resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels. The expansion of the indications to include specific general dermatological, cosmetic, plastic, and reconstructive procedures does not raise any new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 02 2002

Mr. Bruce Prothro
Vice President, Regulatory Affairs
Quality Assurance and Clinical Research
ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085-2936

Re: K020408
Trade/Device Name: Visage® Wands
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 6, 2002
Received: February 7, 2002

Dear Mr. Prothro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: Visage® Wands
510(k) Number: K020408

Indications for Use:

The Visage Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in general dermatology, cosmetic, plastic, and reconstructive surgery including:

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- Development of Skin Flaps
- Skin Tags
- Skin Resurfacing for Treatment of Wrinkles, Rhytides, and Furrows
- Verrucae (Warts)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use ____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020408